

## DETAILED ACTION

This action is in response to amendment filed 11/22/2011 for case 10577541. Claims 1, 4-8, 11, 19, 20, and 32-34 are rejected. Claims 23-25 and 27-31 are withdrawn from consideration. Claims 1, 4, 11, 23, 27, and 32 have been amended. Claims 3, 9-10, 12-18, 21-22, and 26 have been cancelled.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

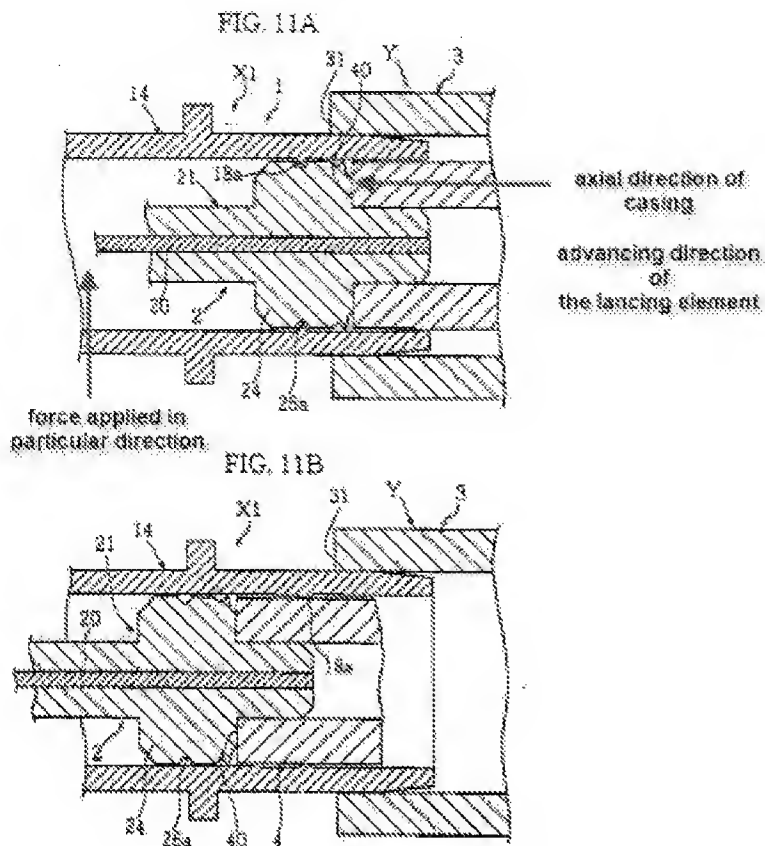
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 4-8, 11 and 32-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Koike et al. (WO 03/005907). Cited element numbers and paragraph numbers are based on US Publication (US 2004/0243165) which is the national stage entry.

Regarding claims 1, Koike et al. disclose a lancet comprising a lancet body (2A, 2B including stopper 71A,71B) provided with a lancing element (20), and a casing (1A, 1B, 12) including a space (10) extending throughout the casing for retaining the lancet body therein (Fig. 20A and 21), wherein the lancet body is fixed to the casing (in the “wait position”) when an external force exceeding a predetermined level in a particular direction is not applied to the casing (paragraphs 81 and 106-110), whereas the lancet

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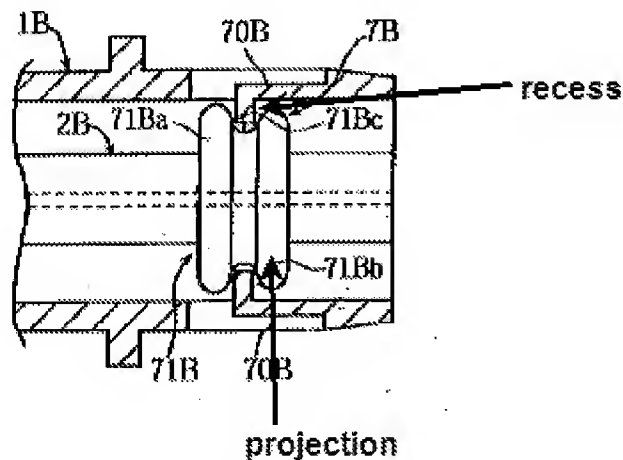
body becomes movable relative to the casing when an external force exceeding the predetermined level in the particular direction is applied to the casing (paragraphs 81 and 106-110), wherein the casing has a cross-sectional shape which changes when the external force exceeding the predetermined level in the particular direction is applied to the casing; and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is changed. The cross-sectional shape changes in the sense that movable pieces (70A) are pushed out of the way allowing the stopper (71A) and the lancet body (2A) to move relative to the casing (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21). Koike et al. disclose the particular direction crosses an axial direction of the casing, and the particular direction is directed from an outside of the casing toward an inside of the casing (Fig 11a and 11b annotated below), the axial direction of the casing being parallel to an advancing direction of the lancing element (when twisting the cap 12 to remove, must apply a compressive force directed in as annotated below to rotate and remove cap to allow lancing element to move, Fig 9a, 9b).



Regarding claim 4, Koike et al. disclose the casing includes a contact portion (70b) which comes into contact with the stopper (71A, 71B) of the lancet body when the external force exceeding the predetermined level in the particular direction is not applied to the casing; and wherein a gap is defined between the contact portion and the lancet body when the cross-sectional shape of the casing is changed. The cross-sectional shape changes in the sense that movable pieces (70A) are pushed out of the way allowing the stopper (71A) and the lancet body (2A) to move relative to the casing (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21).

Regarding claim 5, Koike et al. disclose the contact portion comprises a projection (70b).

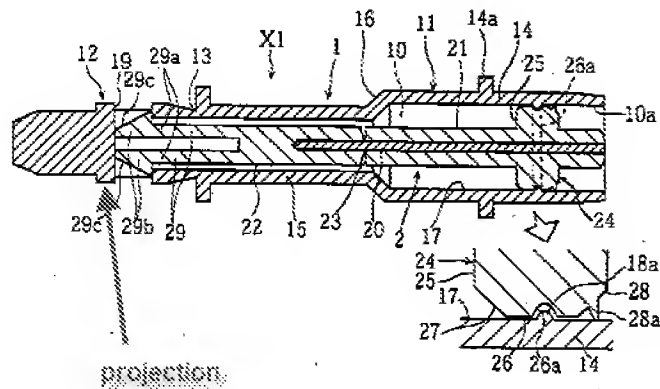
Regarding claim 6, Koike et al. disclose the contact portion comprises a recess (see figure below), and wherein the lancet body is provided with a projection (see figure below) for coming into engagement with the recess (Fig. 21).



Regarding claim 7, Koike et al. disclose an outer diameter of the casing at a portion (14) where the contact portion is not provided is larger than an outer diameter of the casing at a portion where the contact portion is provided (Fig. 10C, 19, 20A).

Regarding claim 8, Koike et al. disclose the casing is formed with a projection (see annotated fig 2 below) for actively causing the external force in the particular direction to be applied to the casing.

FIG. 2



Regarding claim 11, Koike et al. disclose after the cross-sectional shape of the casing is changed, the cross-sectional shape returns to an original shape when the application of the external force to the casing in the particular direction is removed.

Regarding claims 32, Koike et al. disclose a lancet comprising a lancet body (2A, 2B including stopper 71A,71B) provided with a lancing element (20), and a casing (1A, 1B, 12) including a space (10) extending throughout the casing for retaining the lancet body therein (Fig. 20A and 21), wherein the lancet body is fixed to the casing (in the “wait position”) when an external force exceeding a predetermined level in a particular direction is not applied to the casing (paragraphs 81 and 106-110), whereas the lancet body becomes movable relative to the casing when an external force exceeding the predetermined level in the particular direction is applied to the casing (paragraphs 81 and 106-110, twisting the cap 12), wherein the casing is formed with an opening (the space the cap encloses) for allowing a cross-sectional shape to change (when the external force exceeding the predetermined level in the particular direction is applied to

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the casing), the opening reaching at least one end edge of the casing so that said one end edge is divided by the opening; and wherein the lancet body becomes movable relative to the casing when the cross-sectional shape of the casing is changed. The cross-sectional shape changes in the sense that movable pieces (70B) are pushed out of the way allowing the stopper (71A) and the lancet body (2A) to move relative to the casing and the removal of the cap 12 changes the opening cross section shape (paragraphs 81 and 106-110; Fig. 19, 20A, 20B, and 21).

Regarding claim 33, the opening comprises a cutout

Regarding claim 34, Koike et al discloses that when deformed, the opening becomes greater in size as viewed circumferentially of the casing (as the cap is removed, the opening becomes larger due to the removal of the cap and affiliated sleeve 22).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al. (WO 03/005907) in view of Nishikawa et al. (US 6, 315,738).

Regarding claim 19, Koike et al. fail to disclose the casing holds an analytical tool for analyzing a particular component contained in body fluid extracted from a lancing

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target portion. Nishikawa et al. disclose an analytical tool (32), located within the distal end of lancing device, for analyzing a particular component contained in body fluid extracted from a lancing target portion, wherein the analytical tool includes a capillary (33) for moving blood by capillary force, a through-hole for allowing movement of the lancing element, and an introduction port (33a) which communicates with the through-hole for introducing blood to the capillary (Fig. 3 and 4). Nishikawa et al. disclose that providing a detection means such as a test strip within the lancet is advantageous because using one device is more convenient and sanitary than replacing a lancet for a glucose monitoring device (col. 2, ln. 7-12). It would have been obvious to one ordinary skill in the art to modify the casing of the device of Koike et al. to include an analytical tool as taught by Nishikawa et al. in order to provide a more sanitary and convenient technique for testing blood parameters such as glucose levels.

Regarding claim 20, Koike et al. as modified by Nishikawa et al. disclose the analytical tool includes a capillary (33) for moving blood by capillary force, a through-hole for allowing movement of the lancing element, and an introduction port (33a) which communicates with the through-hole for introducing blood to the capillary (Fig. 3 and 4).

### ***Response to Arguments***

1. Applicant's arguments filed 11/22/2011 have been fully considered but they are not persuasive.
2. Regarding the rejection of claims 1, 3-18, and 32-34 by Koike et al, the external force applied to the cap 12 of the lancet changes the cross sectional shape of the

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opening of the casing since the removal of the cap 12 and the sleeve 22 connected to it allow the opening within the casing to increase in size. The removal of the cap subsequently allows the needle of the lancet to become movable and thereby satisfies the claim limitations. Furthermore, the opening of the case goes to the end of the instrument body where the cap 12 is attached and the needle is inserted, so the edge is divided by the opening.

### ***Conclusion***

3. This is a substitution of applicant's earlier Application No. 10577541. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER SCHUBERT whose telephone number is (571)270-1656. The examiner can normally be reached on M-F 7:30-5pm ESD.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 5712724697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. S./  
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11/28/11

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